

REMARKS

Claims 1-6, 10-11, 13-16 and 18 remain pending in this application. No new matter has been added. Based on the following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement is submitted herewith, including an additional office action in related US Patent Application S.N. 10/669,203. Applicant respectfully requests consideration of the documents cited in the information disclosure statement.

Claim Rejections - 35 U.S.C. §103

Claims 1-2 and 6, stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,397,107 ("Lee") in view of U.S. Patent No. 5,749,894 ("Engelson"), and in further view of U.S. Patent No. 5,824,049 ("Ragheb"). Applicant respectfully traverses these rejections, since no proper combination of Lee, Engelson and Ragheb disclose or suggest each of the acts required by these claims.

The Supreme Court set forth the basic test for obviousness in Graham v. John Deere, 383 U.S. 1, 148 (1966). Additionally, the Supreme Court has addressed the issue of obviousness in KSR International vs. Teleflex Inc., 127 S. Ct. 1727 (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness", and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning". While

not specifically addressed by the Supreme Court in KSR, for a combination of prior art references to render a claimed device obvious, a device resulting from the combination of prior art references must still consider **all** of the limitations of that claim (See MPEP §2143).

Further, the Supreme Court in KSR, stated: “A patent composed of several elements is not proven obvious merely by demonstrating that each element was, independently, known in the prior art...it can be important to identified a reason that would have prompted a person of ordinary skill in the relevant field to combined the elements in the way the claimed new invention does”.

Additionally, in Ex parte WHALEN, the BPAI reversed an Examiner’s claim rejections based on obviousness, since the Examiner had not set forth “an adequate basis – based on evidence or scientific reasoning” to support the rejections. The BPAI cited the Supreme Court decision in KSR, and agreed that “obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some ‘apparent reason to combine the known elements in the fashion claimed” (Ex parte Whalen, citing KSR at 1741).

Independent claim 1 recites a method for embolizing a target site in a vasculature of a body, including detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body, the vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the bioactive agent coating; and delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site, wherein the polymeric material at least partially melts or softens so that

the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

Conversely, Lee discloses delivering high frequency energy from outside the body to heat an implanted occlusive device in order to heat and cause the surrounding tissue to coagulate and contract around the device. (Col. 2, lines 50-65). There is no disclosure or suggestion in Lee that the vaso-occlusive device comprises a therapeutic bioactive agent coating or a polymeric material coating substantially covering a bioactive agent coating. Nor is there any disclosure or suggestion in Lee that heating the vaso-occlusive device at least partially melts or softens a polymeric material so that a bioactive agent is released or activated at the treatment site. Nor do Engelson or Ragheb disclose or suggest these missing claim limitations.

Engelson discloses deploying a vaso-occlusive device that is heated preferably by a light-emitting device inside the blood vessel in order to reform or melt a polymer coating over the device that adheres to and stabilizes the vaso-occlusive device. (Col. 1, lines 15-20, Col. 3, line 64 to Col. 4, line 55, Col. 5, lines 5-17, Col. 9, lines 31-41). Again, there is no disclosure or suggestion in Engelson that a therapeutic bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

Ragheb discloses a coated medical implant (i.e. stent) having a layer of a bioactive material (preferably an antithrombotic or anticoagulant agent, such as heparin), covered with a porous layer of a biocompatible polymer that allows a controlled release of the bioactive material (Col. 3, lines 9-65). "The purpose of the porous layer 20 is to provide a controlled released of the bioactive material when the device 10 is positioned in the vascular system of a patient" (Col. 10, lines 31-38). Ragheb discloses that the device is

particularly used in percutaneous transluminal angioplasty to avoid abrupt closure and/or restenosis of a blood vessel by having controlled release of anticoagulants. (Col. 5, lines 47-64). Again, there is no disclosure or suggestion in Ragheb that a therapeutic bioactive agent is released or activated at the treatment site when the medical implant is heated.

There is no reason based on evidence or scientific reasoning, and the office action fails to point out any, that would have prompted a person skilled in the art at the time of filing the present application to combine the teachings of the three cited references to achieve the method of claim 1. Applicant does not concede that there is a reason to combine these references, but even if a person skilled in the art were to combine the teachings of Lee, Engelson and Ragheb, the resulting method would include deploying a vaso-occlusive device at a target site, the device having a coating of a porous polymeric material and a coating of bioactive anticoagulant agent (Ragheb), and delivering energy from a high frequency energy located outside the body (Lee) to thereby heat the vaso-occlusive device at the target site to reform or melt the polymeric coating and stabilize the vaso-occlusive device (Engelson). The bioactive agent would be released due to the porous polymeric coating, as disclosed in Ragheb, prior to heating the device. Thus, the bioactive agent would not be released or activated when the vaso-occlusive device is heated. Therefore, such combination will not produce a method for embolizing a target site in a vasculature of a body, wherein a therapeutic bioactive agent underlying a polymeric material coating is released or activated at the treatment site when the vaso-occlusive device is heated by delivering energy from an energy emitting element located outside the body to thereby melt or at least partially soften the polymeric material.

For at least these reasons, Applicant respectfully submits that independent claim 1 is patentable over the combination of Lee, Engelson, and Ragheb. Dependent claims 2 and 6 incorporate all of the limitations of independent claim 1, and thus are believed to be patentable over Lee, Engelson and Ragheb for at least the same reasons as claim 1.

Claims 3-4, 10-11 and 13 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Lee, Engelson, Ragheb, in further view of U.S. Pub. 2004/0215124 (“Yamasaki”). The office action states that the combination of Lee, Engelson and Ragheb disclose the claimed invention except having a magnetic resonance imaging (MRI) device to apply magnetic field (Yamasaki). Applicant respectfully disagrees.

As discussed above, the combination of Lee, Engelson and Ragheb does not disclose or suggest all of the limitations of independent claim 1, and such combination does not disclose or suggest the all the limitations of independent claim 10 for the same reasons. In particular, the combination of Lee, Engelson and Ragheb does not disclose the acts of “heating a highly resistive element in the vaso-occlusive device and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent.” Nor does Yamasaki teach or suggest these missing claim limitations.

Yamasaki discloses introducing an irritant in serum form into the aneurysm, causing the aneurysm to shrink “*over the course of several days or weeks*” (Yamasaki, paragraph 62 - 66). Although, MRI may be used to cure the irritant in Yamasaki, a method combining Lee, Engelson, Ragheb with Yamasaki, would not yield each and every limitation of respective claims 3-4, 10-11 and 13. Certainly, Engelson does not suggest why, neither the office action states any apparent reason for such modification of a MRI use would be

desirable because Engelson's method preferably uses a light-emitting device in order to reform the polymers, and does not release or activate therapeutic bioactive agents.

Regarding claim 4, the office action states (on page 5) that "it would have been obvious... to provide a vaso-occlusion device comprising a ferrous material that responds to applied energy so that the device remains cohesive... and therefore properly treating the target site." However, there is no mention in claim 4 of the ferrous material causing the device to be (or remain) "cohesive."

Regarding claim 11, which recites that the heating of the device causes coagulation of the blood, Ragheb repeatedly discloses anticoagulants (i.e. heparin) as the bioactive material coating and avoiding abrupt closure and/or restenosis of a blood vessel.

For at least these reasons, claims 3-4, 10-11 and 13 are believed patentable over the combination of Lee, Engelson and Yamasaki.

Claim 5 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lee in view of Engelson, in further view of Ragheb and still in further in view of U.S. Patent No. 6,740,094 ("Maitland"). Applicant respectfully disagrees.

Maitland discloses the activation and expansion of a shape memory actuator when heated to remove blockages in a blood vessel, wherein the energy delivered to the actuator may be ultrasounds waves (Col 6, lines 26-57). Lee, Engelson and Ragheb do not disclose all the limitations of independent claim 1, as discussed above, and having an energy source comprising an ultrasound device, as disclosed in Maitland, does not provide the missing claim limitations. Thus, claim 5 is believed patentable over the combination of Lee, Engelson and Maitland.

Claims 14-16 and 18 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Lee, in view of Engelson, in further view of Ragheb still in further view of U.S. Patent No. 5,853,418 (“Ken”). Applicant respectfully disagrees.

As discussed above, the combination of Lee, Engelson and Ragheb does not disclose or suggest all of the limitations of independent claims 1 or 10, nor does their combination disclose or suggest the limitations of independent claim 14, for at least the same reasons. In particular, the combination of Lee, Engelson and Ragheb does not disclose the acts of “heating the highly resistive element and, by way of convective heat transfer from the highly resistive element, heating the coil thereby at least partially melting or softening the polymeric material and releasing or activating the bioactive agent.” Nor does Ken teach or suggest these missing claim limitations.

Ken discloses a stretch-resisting member for a vaso-occlusive coil device that may “optionally contain modest amounts of iron.” (Col. 5, lines 1-2). However, there is no disclosure or suggestion in Ken that such “modest amounts of iron” in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to energy transmitted by external energy emitting element after detachment of the coil, as required by independent claim 14. Ken discloses releasing a vaso-occlusive coil in a treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62), which is different than heating the already detached and implanted coil by application of energy transmitted by an energy emitting element located external to the patient.

Again, the combination of Lee, Engelson, Ragheb and Ken does not disclose or suggest a method for embolizing an aneurysm in a body, including all the acts recited in

claim 14. There is no evidence that Ken's "modest amounts of iron" would cause the stretch-resisting filament of Ken to act as a heating member if exposed to energy transmitted by external energy emitting element of Lee. Furthermore, there is no disclosure in Lee, Engelson and Ragheb that the bioactive agent would be released or activated by heat.

Regarding claim 16, recites the heating of the device to cause blood coagulation, which teaches away at least from the disclosure of Ragheb, which repeatedly discloses anticoagulants (i.e. heparin) as the bioactive material coating and avoiding abrupt closure and/or restenosis of a blood vessel.

For at least these reasons, independent claim 14 is believed patentable over the combination of Lee in view of Yamasaki. Dependent claim 15, 16 and 18 are also believed patentable over such combination, for at least the same reasons.

CONCLUSION

In view of the foregoing remarks, allowance of all remaining claims is respectfully requested. If the Examiner believes that a telephone interview could expedite resolution of any remaining issues, she is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,
VISTA IP LAW GROUP LLP

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By: /DavidTBurse/
David T. Burse
Reg. No. 37,104

Customer Number
41696
PATENT TRADEMARK OFFICE

VISTA IP LAW GROUP LLP
12930 Saratoga Avenue, Suite D-2
Saratoga, CA 95070
Phone (408) 777-2905
Fax (408) 877-1662